

May 2, 2008

Ms. Fran Kammerer
Staff Counsel
Office of Environmental Health Hazard Assessment
1001 "I" Street
Sacramento, California 95812

Re: Comments to Beneficial Nutrient Draft Regulations

Dear Ms. Kammerer:

I am submitting these comments on behalf of several of my clients, in response to the subject notice published by the Office of Environmental Health Hazard Assessment ("OEHHHA" or the "Agency") on March 21, 2008.

A regulation, to be valid, has to satisfy the statutory standards and procedural requirements set out in the California Administrative Procedure Act. Government Code sections 11340 and following. The statutory standards (1) require the agency to demonstrate the necessity for a proposed regulation and (2) require the regulations to be consistent with the statutory provisions that are being implemented, interpreted or made specific.

The discussion at the workshop on April 18th demonstrated that no currently listed Proposition 65 chemical would be affected in any way by the draft beneficial nutrient regulation. Also, the discussion at the April 18th workshop demonstrated that no relationship exists between RDAs and 20% of the Upper Intake Level and cancer or reproductive risk for most of the beneficial nutrients.

In addition, the draft regulation is inconsistent with the intent and literal language of Proposition 65. Proposition 65 requires a warning to exposures of chemicals known to cause cancer or reproductive harm unless the exposure poses no significant risk for carcinogens and is below one one-thousand of the no observable effect level for reproductive toxicants. OEHHHA staff made clear during the April 18th workshop that the proposed exposure levels are significantly higher than the allowable exposure, certainly for reproductive toxicants. This inconsistency would render the regulation invalid.

SAC 441,229,639v1 5/2/2008

OEHHA Cannot Demonstrate the Necessity for the Draft Regulation

The APA sets out the standards for necessity. Government Code section 11342.2 provides as follows:

Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective unless consistent and not in conflict with the statute and **reasonably necessary to effectuate the purpose of the statute.** (Emphasis added.)

Government Code section 11349 defines "necessity" to mean, "the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion."

The Office of Administrative law has adopted regulations implementing, interpreting, and making specific provisions of the APA. It sets out in section 10, Title 1, of the California Code of Regulations how it applies the necessity standard. In subdivision (b) it provides:

"In order to meet the "necessity" standard of Government Code section 11349.1, the record of the rulemaking proceeding shall include:

(1) A statement of the specific purpose of each adoption, amendment, or repeal; and

(2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An "expert" within the meaning of this section is a person who possesses special skill or knowledge by reason of study or experience which is relevant to the regulation in question."

No Listed Chemical Would Be Affected By the Draft Regulation

During the April 18th workshop, two chemicals were identified that might be affected by the draft regulation. These two chemicals were Vitamin A and Chromium.

Vitamin A is a beneficial nutrient. On the other hand, the Chromium that is listed as a Proposition 65 chemical is Chromium 6. Chromium 3 is a beneficial nutrient. Chromium 6 and Chromium 3 are entirely different chemicals.

Since Vitamin A is a listed Proposition 65 chemical and is a beneficial nutrient, it might be concluded that the draft regulation would have some effect with respect to Vitamin A. However, as was discussed during the April 18th workshop, the listing of Vitamin A eliminates any need for the draft regulation. It is not Vitamin A itself that is included on the Proposition 65 list of chemicals. Rather, it is Vitamin A in excess of 10,000 international units. Vitamin A was listed in this fashion, recognizing its importance as an essential human nutrient and its importance to a developing fetus, while acknowledging that excessive amounts pose a risk. The draft regulation, however, would set an exposure level that is at or below 10,000 IUs.

The draft regulation would have no effect on exposures to Chromium since the beneficial nutrient Chromium is a different chemical than the Proposition 65 listed Chromium. The draft regulation would have no effect on exposures to Vitamin A since it proposes to set an exposure level that is at or below the amount of Vitamin A that is a listed reproductive toxicant. Hence, no necessity exists for the draft regulation.

Possible Future Action Does Not Provide A Basis for Necessity

During the April 18th workshop, OEHHA staff expressed the view that in the future, some beneficial nutrient might be added to the Proposition 65 list. No specific substances were mentioned; no specific timeframe was provided; no supporting facts, studies, expert opinion, or other information was referenced.

As noted above, the necessity for a regulation cannot be based on speculation or conjecture. “. . . the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information.”

The requirements of the APA and the implementing regulations have not and cannot be satisfied by OEHHA. No necessity exists for adopting the draft regulation.

OEHHA Cannot Demonstrate Necessity for Each of the Exposure Levels

The draft regulation would exempt exposures in foods for which no warning is required at the RDA or 20% of the Upper Intake Level. To meet the necessity standard, OAL would have to provide information explaining why each of those levels is required to carry out the purposes of Proposition 65.

The purpose of Proposition 65 is to provide a warning before California residents are exposed to a chemical known to the State of California to cause cancer or reproductive harm. Hence, to meet the necessity standard, OEHHA would be required to demonstrate the relationship of each proposed exposure level to either cancer or reproductive harm. OEHHA cannot meet this burden.

During the April 18th workshop, numerous commenters pointed out that the RDA is the recommended intake for each nutrient that meets the requirements for most healthy people. The RDA recognizes and the body establishing the RDA recognizes that some people will ingest more. In addition, the RDAs are set to promote good health. They are not set on the basis of risk to cancer or reproductive harm.

Similarly, the Upper Intake Levels are set with only a few exceptions on the basis of outcomes other than cancer or reproductive harm. These outcomes include the following:

Vitamin B6	Sensory Neuropathy
Calcium	Milk-Alkali Syndrome
Vitamin D	Hypercalcemia
Fluoride	Dental Enamel Flurosis

More significantly, a level that is only 20% of the Upper Intake Level bears even less of a relationship to risk of cancer or reproductive harm. While it is impossible to demonstrate the necessity for the RDAs and Upper Intake Levels to implement Proposition 65, basing exposure at 20% of the Upper Intake Level only exacerbates the impossible.

During the April 18th workshop, OEHHA staff acknowledged that the 20% level was arbitrary. A rationale given was that 20% of the Upper Intake Level roughly correlates to the RDA where both exist for certain beneficial nutrients.

In fact, any similarity between 20% of the Upper Intake Level and an RDA is purely coincidental. The chart set out below will illustrate how disparate these values are.

Nutrient	RDA (adults)	20% of UL
Vitamin E (mg/day)	15	200
Copper (µg/day)	900	2,000
Molybdenum (µg/day)	45	400
Iodine (µg/day)	50	400
Vitamin B6 (mg/day)	1.3 - 1.7	16-20
Vitamin C (mg/day)	M 90 / F 75	400
Niacin (mg/day)	M 16 / F 14	7
Selenium (µg/day)	55	80

The Draft Regulation Is Inconsistent with Proposition 65

Government Code section 11342.2 sets out the requirements for a regulation to be found valid. It provides as follows:

Whenever by the express or implied terms of any statute a state agency has authority to adopt regulations to implement, interpret, make specific or otherwise carry out the provisions of the statute, no regulation adopted is valid or effective **unless consistent and not in conflict with the statute** and reasonably necessary to effectuate the purpose of the statute. (Emphasis added.)

Government Code Section 11349 defines consistency to mean “being in harmony with, and not in conflict with or contradictory to, existing statutes, court decisions, or other provisions of law.”

The draft regulation, to survive a legal challenge, has to be consistent with the statutory provisions of Proposition 65. The purpose of the draft regulation is to eliminate the need for the person causing an exposure to a beneficial nutrient to provide a warning as long as the exposure does not exceed the RDA or 20% of the Upper Intake Level.

Proposition 65 specifically addresses the circumstances when no warning is required for an exposure to a listed chemical. The statute itself provides that no warning is required for exposures to listed carcinogens when the exposure poses “no significant risk,” assuming a lifetime exposure. (Health & Safety Code section 25249.10) No warning is required for exposures to developmental and reproductive toxicants that would have no observable effect, assuming an exposure that is 1,000 times the level in question. (Health & Safety Code section 25249.10)

OEHHA's Authority to Define "No Significant Risk" Lends Some Support to the Draft Regulation Applied to Carcinogens

As noted above, no warning is required if an exposure to a carcinogen falls below the no significant risk level. Since the statute contains no definition of "no significant risk," OEHHA has the legal flexibility to define that phrase. In effect, that is what the draft regulation does. It defines no significant risk as exposures to listed chemicals in food products at or below either the RDA or at 20% of the Upper Intake Level.

OEHHA has the authority to define no significant risk. It has done so in the existing regulations, specifically reserving the right to set different levels for foods as an example. It also relied on that authority when it sought to address the acrylamide issue by defining what level of acrylamides in certain food products pose no significant risk.

It should be noted that certain interest groups have taken the position in the past that the regulatory authority to define no significant risk is limited. The original regulations included a provision that was mischaracterized as the FDA exemption. Rather, that provision defined no significant risk to exclude listed chemicals in FDA regulated products as long as the products met all state and federal health standards. In a case called *Duke II*, several plaintiff groups challenged the regulation. The trial court upheld their challenge, and the state settled, agreeing to repeal the provision while the case was pending on appeal.

OEHHA Has No Authority to Modify the Thousand-Fold Uncertainty Factor for DARTs

While OEHHA has the authority to define no significant risk levels for exposures to carcinogens, the statute defines the level at which exposures to developmental and reproductive toxicants require a warning. That level of course is one one-thousandth of the no observable effect level. Accordingly, the draft regulation cannot be supported by the argument that OEHHA can achieve the same result by setting a maximum allowable dose level.

The question then is how would a court view a regulation that eliminates warnings for exposures that are substantially more than one one-thousandth of the NOEL. In fact, the draft regulation would provide that no warning is required for an exposure that may be as much as one-tenth or even one-half of the NOEL.

During the April 18th workshop, OEHHA staff explained that the draft regulation would produce exposure levels significantly above the levels that would result from applying the one one-thousandth safety factor to no observable effect levels. In fact, the reason given for the draft regulation was to allow exposures, significantly higher than those produced by the one one-thousand fold safety factor without requiring warnings.

The regulation directly conflicts with the specific provisions of Proposition 65. That initiative measure requires a warning for exposures to a chemical known to the State of California to cause cancer or reproductive harm. The principal exception is if the exposure to a listed carcinogen poses no significant risk and if an exposure to a listed reproductive toxicant is one one-thousandth below the no observable effect level. A regulation that provides that no warning is required for exposures that may be significantly higher than the no significant risk level or one one-thousandth of the no observable effect level, is inherently inconsistent.

A court might construe the exposure levels contained in the draft regulation for carcinogens as a definition of no significant risk. However, as noted above, that approach has major legal vulnerabilities as well. A trial court previously invalidated the definition of no significant risk that applied to exposure to listed chemicals in products that met state and federal agency health standards. The RDAs and Upper Intake Levels are set by a body that is more removed from the jurisdiction of agencies dedicated to protecting the public health.

No argument can be made for the regulation exempting exposures to beneficial nutrients listed as reproductive toxicants (if any ever are). OEHHA has no authority to modify the one one-thousand fold safety factor. The statute is explicit. Warnings must be given to exposures that exceed one one-thousandth of a no observable effect level. The effect of the draft regulation is directly inconsistent with Proposition 65. As such, it is invalid.

Conclusion

For the reasons set out above, OEHHA should take no further steps to pursue a regulation exempting exposures to beneficial nutrients.

Sincerely,

GENE LIVINGSTON

GL/sma